

# A novel model of acellular dermal matrix plug for anal fistula treatment. Report of a case and surgical consideration based on first utility in Poland

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## ABSTRACT:

Anal fistula (AF) is a pathological connection between anus and skin in its surroundings. The main reason for the formation of anal fistula is a bacterial infection of the glands within the anal crypts. One of the modern techniques for the treatment of fistulas that do not interfere with the sphincters consists in implantation of a plug made from collagen material. We are presenting the first Polish experience with a new model of biomaterial plug for the treatment of anal fistula. We also point out key elements of the procedure (both preoperative and intraoperative) associated with this method. In the authors' opinion, the method is simple, safe and reproducible. Innovative shape of the plug minimizes the risk of its migration and rotation. It also perfectly blends with and adapts to the course and shape of the fistula canal, allowing it to become incorporated and overgrown with tissue in the fistula canal. The relatively short operation time, minor postoperative pain and faster convalescence are with no doubt additional advantages of the method. Long-term observation involving more patients is essential for evaluation of the efficacy of the treatment of fistulas with the new type of plug.

## KEYWORDS:

anal fistula, biomaterial plug, plug implantation

## INTRODUCTION

Anal fistula (AF) is a pathological connection between anus and skin in its surroundings.

The main reason for the formation of anal fistula is a bacterial infection of the glands within the anal crypts. Other reported causes include Crohn's disease, the presence of a foreign body, trauma in the scrotal region as well as iatrogenic injuries and injuries caused by therapeutic irradiation of the pelvic region. According to recent population studies carried out in European countries (England, Germany, Spain, and Italy), the incidence of anal fistulae ranges between 12 and 28 cases per 100,000 individuals [1]. According to the Parks' classification system, fistulae are distinguished by their course relative to the external anal sphincter muscle to include: 1) intersphincteric fistulae, 2) trans-sphincteric fistulae, 3) suprasphincteric and extrasphincteric fistulae [2].

The main guidelines for surgical treatment of anal fistulae include elimination of inflammation and bacterial infection, elimination of the fistula canal depending on the surgical method (incision, resection, ligation, closure) with minimal interference with the anal sphincter apparatus which might potentially lead to postoperative incontinence of gas and/or stool.

Surgical procedure is largely dependent on: 1) the etiology of the fistula, 2) the shape of the fistula, 3) history of perianal procedures, 4) the experience of the surgical team, and 5) available equipment. Surgical treatment is the method of choice. Most common techniques include fistula resection (fistulectomy), incision (fistulotomy) loose or cutting seton drainage and fistulectomy with closure of the inner opening by a mucoso-muscular or anodermal flap. Recent years saw the introduction of techniques aimed mainly at avoiding interference with the sphincter apparatus so as to minimize the incidence of potential complications such as sphincter

failure and incontinence. Most common sphincter-sparing techniques include ligation of intersphincteric fistula tract (LIFT), video-assisted anal fistula treatment (VAAFT), laser techniques (e.g. FiLac™), tissue cements and plugs.

The wide range of available surgical methods and the continued search for novel solutions are in fact a reflection of difficulties associated with the treatment of anal fistulae due to their heterogeneity in terms of type and etiology as well as to the lack of a single method that could be recommended as efficient and associated with low risk of postoperative complications.

Previous unsatisfactory outcomes of anal fistulae being treated by biomaterial plugs were due to discrepant methodologies (ambiguous implantation and fixation techniques), diversity in fistular origins and the heterogeneity of fistular types. The 2007 Chicago consensus systematized the indications and recommended that biomaterial plugs be used in trans-sphincteric fistulae which constitute the ideal type of fistulae for the use thereof [3].

According to independent studies conducted by Schwandner et al. and Zubaidi et al., treatment of fistulae using biomaterial plugs is efficient in 62% and 83% of cases, respectively [4,5].

In addition, as demonstrated by McGee et al., the length of the fistular canal is a statistically significant factor determining the efficacy of the treatment using collagen plugs [6].

Below is the first Polish experience with the new model of biomaterial plug for use in the treatment of anal fistulae. Our own observations and practical recommendations for implementation of the method based on the new model of implanted material are also presented.

## CASE REPORT

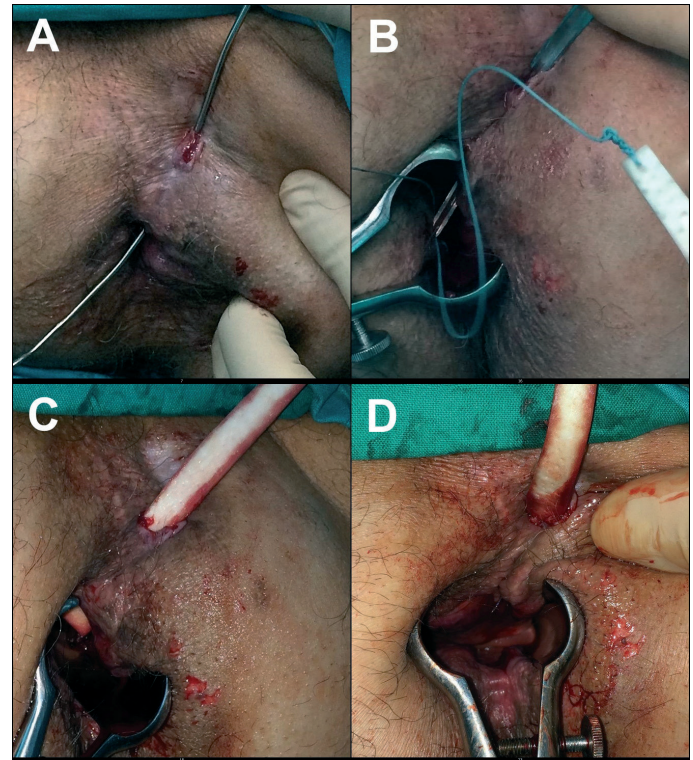
A 63-year-old male patient with anal fistula was admitted to the Department for surgical treatment of the condition. Trans-sphincteric fistula was confirmed in diagnostic imaging (fistulography and transrectal ultrasound scan). Loose seton drainage was performed for two months prior to patient being qualified for surgical procedure.

The patient was operated in Lloyd-Davies position under subarachnoid block. Second-generation cephalosporin and metronidazole were used in perioperative prophylaxis. Intrarectal infusion was performed as a part of patient preparation on the day before and the day of surgery. The internal opening of the fistula within the anal lumen was visualized using a probe introduced through the external opening (Photo 1A). The fistular lumen was rinsed with hydrogen peroxide solution. Curretage of the fistular lumen was performed. In the meantime, a *Pressfit*<sup>®</sup> (DecoMed, Venice, Italy) plug was placed in physiological saline for 10 minutes to increase the elasticity of the biomaterial. Mucosal flap was dissected within the internal opening region for future coverage of the plug implanted within the internal opening. A guide thread was attached to the distal (i.e. narrower) end of the implant and to the probe introduced through the fistular lumen (Photo 1B). Next, the plug was inserted into the fistula by being pulled from the internal opening until securely fixated within the fistular lumen. Excess implant material was cut off at both the internal and the external opening. The plug was fixated in the internal opening region using a 2-0 absorbable suture to the internal anal sphincter muscle. Next, the implant was covered by the mucosal flap stitched around with the 2-0 absorbable suture (Photo 1C and Photo 1D). The external opening was left to heal "in the open" with the skin in the opening region being additionally incised to facilitate evacuation of serosanguineous content. The total time of surgery was 45 minutes. In the postoperative period, the patient received lactulose 15 mL once a day. Sitz baths were also administered. The patient was discharged from the hospital on the second day after surgery. Serous drainage was observed for 2 months in the external opening region. Patient reported no pain upon defecation and no feeling of foreign body within the anal region. The outcomes of the treatment as monitored in the follow-up period are presented in Photo 2.

## DISCUSSION

In 2007, Johnson et al. presented their first observations on the use of biomaterial anal plug in the treatment of anal fistulae [7]. Introduction of this innovative method ideally corresponded to the common principle of surgical treatment of anal fistulae that is to ensure a possibly most radical management without excessive intervention within the sphincter apparatus. According to the recent retrospective analysis carried out in Poland, 9.51% of surgeons affiliated with the Polish Surgical Society use collagen plugs in the treatment of anal fistulas [8].

The new acellular collagen plug is innovative due to their shape as well as physicochemical parameters. The collagen matrix is a non-crosslinked structure that maintains the integrity of native proteins and provides a natural scaffold for the surrounding fis-



**Fig. 1.** Collagen plug insertion procedure stages.

- A—fistular canal and openings;
- B—fixation of a thread connected to the probe inserted through the fistular lumen;
- C—insertion and absorbable suture fixation of the plug to the internal sphincter muscle;
- D—mucosal flap coverage of the internal opening with the implanted plug.

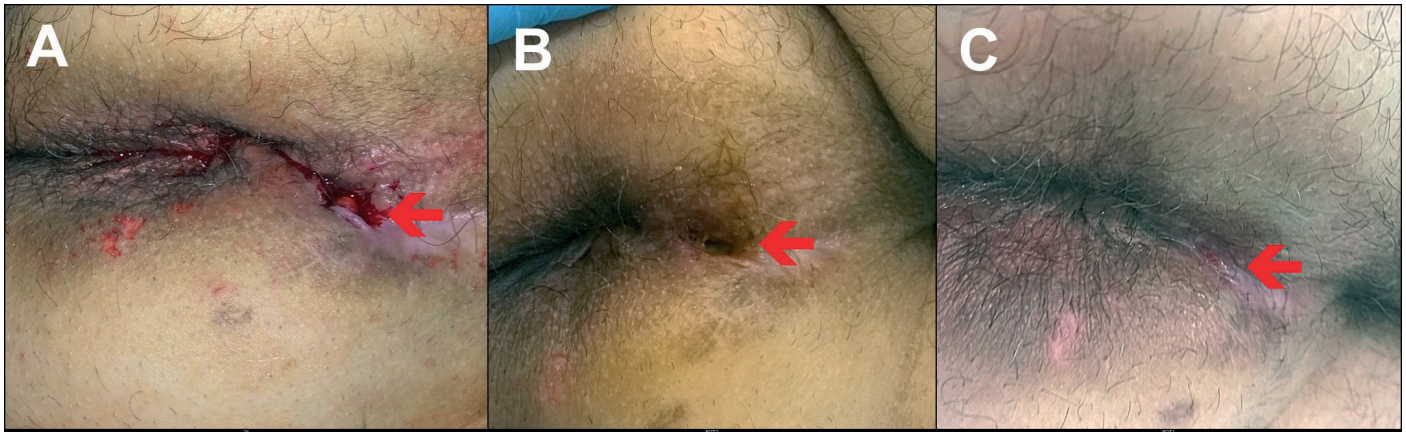
tular canal tissues thus facilitating its overgrowth and incorporation within the lumen.

According to a systematic review by Garg et al., the treatment of anal fistulas using collagen plugs is characterized by success rate of 59.9% [9]. Based on the above analysis, the authors conclude that the anal plug technique is safe and characterized by low rates of complications and infections within the surgical site.

In their analysis of the success rates of biomaterial plugs in a homogeneous group of patients (trans-sphincteric fistulae with cryptic etiology), Heydri et al. demonstrated a 69% efficacy rate in a 12-month follow-up period [10]. Similar results were obtained by Ratto et al. who observed a success rate of more than 72% [11].

Also in the opinion of the authors of this study, the anal plug method is safe and repeatable in its technical aspect. It is associated with short convalescence period, low pain levels, and, very importantly, reduced probability of injury to the sphincter apparatus. Methods not interfering with the sphincter mechanism are postulated with an increasing frequency in early surgeries within the anal region, recurrent anal fistulas, as well as in patients with reduced sphincter tone [12].

O'Connor and Champagne demonstrated no correlation between preoperative loose seton drainage and the efficacy of fistular plug treatment [13,14]. Based on our own experience in the treatment of anal fistulas, we believe that the seton drain-



**Fig. 2.** External opening of the treated fistula A – immediately after the surgery, B – 2 days after the surgery, C – 2 months after the surgery.

**Tab. I.** Most important factors that determine the efficacy of the novel collagen plug

PREOPERATIVE	PERIOPERATIVE	POSTOPERATIVE
Appropriate selection of patients in terms of fistular etiology	Flushing the fistular lumen	Prevention of constipation
Determination of fistular type	Thorough curettage	Decontamination of the external opening
Types of previous procedures and the potential cause for recurrence	Covering the internal opening with a mucosal flap	
Seton drainage preparation required	Implant fixation	
Preparation for the procedure (enema, antibiotic prophylaxis)	Broadening the external opening	

age is necessary and should constitute the first stage of most anal fistula treatment procedures. This belief is in line with the opinions of most experts who consider the seton drainage to be a major factor determining the success of biomaterial treatment approaches [11,15]. The aforementioned studies by O'Connor et al. and Champagne et al. are unanimous since they were conducted in the same period and at the same site. However, the population of patients in these studies was not homogeneous and included Crohn's disease patients. The treatment of fistulas in the course of Crohn's disease is by its nature associated with a high risk of recurrence amounting to 48% and 59% for one- and two-year follow-up period after initial fistula treatment [16].

In our opinion, seton drainage as a stage to prepare the fistular canal minimizes inflammation, reduces the signs of infection within the fistular lumen as well as facilitates sharp definition of lumen edges for safer and more secure implant placement.

Portilla et al., who implanted the biomaterial without previous seton draining preparation, were able to demonstrate the treatment success rate of as little as 16% (3/19) which led them to an unambiguous conclusion that preoperative seton draining is a prerequisite for treatment success [15].

Plug migration is one of the most commonly reported causes of treatment failure [17]. Due to the innovative shape of the plug which mimics the spatial organization of endoprosthesis shafts, the modified plug profile appears to prevent the material from rotating around its axis and thus becoming loosened within the fistular lumen as reported for biomaterials of prior art [18].

In the largest material published on the new plug type, the efficacy of treatment defined as the lack of recurrence was reported in 75% of patients in a 9-month follow-up period [19]. A character-

istic feature of the collagen plug implantation procedure consists in the secretion of serous or serosanguineous from the external opening of the fistula in the postoperative period. This is associated with the presence of a biological material as such, the preceding curettage procedure, as well as with the material being incorporated and overgrown by the fistular lumen tissues. Drainage was reported for as long as 12 months after implantation of biomaterial with no clinical sign of fistular recurrence [19].

Table 1 presents the key elements of pre-, peri-, and postoperative management which, in the opinion of authors, increase the efficacy of the treatment using a biomaterial plug and reduce the risk of recurring fistula.

## CONCLUSIONS

The novel type of collagen anal plug is characterized by simple and repeatable implantation. The authors believe that besides appropriate selection of patients in terms of the etiology and type of the fistula, an important element of the procedure consists in preoperative seton drainage of the fistular lumen. According to the authors, appropriate, long-term (1-2 months) is crucial for the treatment success. Owing to the innovative shape of the prosthesis, the method is characterized by the simplicity of implantation and stability of fixation. An unquestionable advantage of the method consists in its being non-invasive with regard to the sphincter apparatus. Although the success rates for the treatment of anal fistulas using the older type of collagen plugs range between 60 and 70%, it appears that the innovative profile, shape, and cross-linking of the novel type of plug may contribute to the increase in treatment efficacy. Long-term observation involving more patients is essential for more unambiguous evaluation of the efficacy of the treatment of fistulas with the new type of collagen plug.

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